

## REMARKS

Claims 23-42 have been canceled without prejudice or disclaimer. Claims 43-62 have been added and therefore are pending in the present application. Claims 43-62 are supported throughout the specification, including the original claims.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### I. The Objection to Claims 23, 24 and 26-42

Claims 23, 24, and 26-42 are rejected under 35 U.S.C. 112 because they contain subject matter that was non-elected. Claims 23, 24 and 26-42 have been canceled without prejudice or disclaimer. Furthermore, the newly presented claims are directed to the elected subject matter. Therefore, this rejection is rendered moot.

### II. The Rejection of Claim 23 under 35 U.S.C. 112

Claim 23 is rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. This rejection is respectfully traversed.

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). The test is not whether one of ordinary skill in the art envisions all of the claimed subject matter, as suggested in the Office Action.

Applicants submit that the specification provides a written description of the claimed invention. The claimed invention is directed to mutant *Bacillus licheniformis* cells which secrete at least 5% less of a secreted polypeptide than the parent host cell when they are cultivated under comparable conditions, wherein the secreted polypeptide has an amino acid sequence which is at least 90% identical to SEQ ID NO: 134. As explained in the specification, the object of the present invention is to reduce or eliminate secreted polypeptide(s) to provide for a cleaner culture.

It is well established in the art that there is a definitive relationship between protein function and % identity at the amino acid level. Percent identity is highly predictive of protein

function and without this tool it would be impossible to make meaningful annotations of genomes in sequencing projects. Proteins that share 90% amino acid identity are known to possess the same catalytic/biochemical function which has formed the basis for genome annotation and comparative genomics. In fact, 90% identity is an extremely conservative criterion for judging functional similarity. Moreover, it is well within the skill in the art to identify the amino acids which can be modified and still retain the function as a secreted polypeptide.

The Office states that "there is disclosed only deletions of the gene encoding SEQ ID NO: 134, which would result in at least 5% less of the secreted polypeptide." This is respectfully traversed.

It would be apparent to persons skilled in the art that other mutations would result in at least 5% less of the secreted polypeptide. For example, one skilled in the art would appreciate that a substitution of the start codon ATG would result in at least 5% less of the secreted polypeptide.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

### III. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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